4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0477]

Agency Information Collection Activities; Announcement of Office of Management and Budget

Approval; Investigational Device Exemptions Reports and Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Investigational Device Exemptions Reports and Records" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: On January 3, 2013, the Agency submitted a proposed collection of information entitled "Investigational Device Exemptions Reports and Records" to

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OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor,

and a person is not required to respond to, a collection of information unless it displays a

currently valid OMB control number. OMB has now approved the information collection and

has assigned OMB control number 0910-0078. The approval expires on March 31, 2016. A

copy of the supporting statement for this information collection is available on the Internet at

http://www.reginfo.gov/public/do/PRAMain.

Dated: April 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-09481 Filed 04/22/2013 at 8:45 am; Publication Date: 04/23/2013]